

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Liam McDowell on February 12, 2010.

The application has been amended as follows:

Claim 45:

A prefilled syringe configured for the parenteral injection of a semi-solid formulation, comprising:

a longitudinally continuous hollow element forming a reservoir, prefilled with a semi-solid preparation to be injected;

a piston having a convex tip for pressing against the semi-solid preparation to be injected;

a needle at one end of said hollow element, said needle having a supporting base, said semi-solid preparation being between ~~a piston having a~~ said convex tip and ~~a said supporting~~ base of said needle, said supporting base ~~of said needle supporting said needle and~~ directly contacting an entirety of one end face of said hollow element, so that when the piston comes into direct contact with said base of said needle, an entire dose contained in said reservoir is injected; and

a casing which houses said hollow element and provides mechanical resistance of the syringe, said hollow element and said needle being held fastened to each other at said base of said needle, ~~by a said casing which houses said reservoir, and providing mechanical resistance of the syringe,~~

wherein said casing forms a peripheral shell surrounding an external surface of said ~~reservoir with substantially zero clearance~~ hollow element so that an internal surface of said casing directly contacts said external surface of said hollow element along an entirety of said external surface, and

wherein said casing axially forces said hollow element directly against said base of said needle and strengthens said hollow element against radial pressures generated by said axial forces and generated by the ejection of said semi-solid formulation.

Cancel claims 46 and 47

Reasons for Allowance

2. The following is an examiner's statement of reasons for allowance:

The subject matter of the independent claims could either not be found or was not suggested in the prior art of record. The subject matter not found for the independent claims were a pre-filled syringe with a reservoir filled with a semi-solid

formulation, a piston having a convex tip, a needle attached to a supporting base that directly connects to an entirety of one end face of the reservoir and a casing that forms a peripheral shell surrounding the external surface of the reservoir. The piston and the supporting base come into direct contact so that the entire dose of semi-solid formulation is injected. The casing strengthens the reservoir since the casing is in direct contact and envelop the entire outer surface of the reservoir.

The independent claims also include other patentable subject matter in combination with the other elements or steps of the claim not mention in the above paragraph.

The cited prior art of Yamashita fails to show the entire outer surface of the reservoir being in direct contact of the casing, since the casing in Yamashita tapers and leaves a space between the casing and reservoir (see figure 1), which would increase the chance of damaging the reservoir.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Election/Restrictions

3. The restriction requirement based on the election of Species has been reconsidered in view of the allowability of claims to the elected invention and has been **withdrawn as to any claim that requires all the limitations of an allowable claim.**

4. In view of the above noted withdrawal of the restriction requirement, applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW F. DESANTO whose telephone number is (571)272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Matthew DeSanto
/Matthew F DeSanto/
Primary Examiner, Art Unit 3763